All claims pending in this application, claims 9-42, have been cancelled and new claims 43-75 have been added. In order to clearly distinguish the present invention the additional limitation of "alkyl phosphate-free detergent solution" has been added to the claims. Support for this added limitation can be found in several parts of the specification. For example, the Examiner's attention is drawn to page 7, first full paragraph beginning at line three. "If detergents are used as chemical agents, according to a preferred embodiment they are used *without the addition of other agents*, in particular without the addition of *toxic organic substances or solvents, such as, e.g., TNBP.*[1] (Emphasis added). See also Example 6 at page 22 beginning at line 4 through page 25. Specifically, the Examiner's attention is drawn to the exemplary in which the present inventors compare the new inactivation protocol of the present invention with the prior art. Beginning at line 10 on page 24 "[f]or a comparison, factor VII was separated from other proteins of the prothrombin complex by adsorption on aluminum hydroxide as described above, and in the adsorbed state treated...with the virus inactivating agents...tris-(N-butyl)-phosphate (TNBP)."

Therefore, support for all of the elements in the present claims are found in the original specification. No new matter was added.

IN THE SPECIFICATION

The Examiner has required that all references to trademarks used in the specification be capitalized and accompanied by the generic terminology consistent with MPEP section 608.01 (v). Specifically, the examiner has objected to the use of TWEEN® and TRITON®. Therefore, the Applicants request that the following changes be made to the specification. The Applicants assert that no new matter has been added by these changes.

Page 6, line 25 through page 7 line 2, delete the entire paragraph.

Page 6, line 26, insert --Generally, non-ionic detergents are milder and do not denature proteins. Examples of suitable non-ionic detergents used in accordance with the teachings of the present invention include, but are not limited to, TWEEN® (a registered trademark of Atlas

[1] TNBP is tri-n-butyl phosphate a common alkyl phosphate known to those skilled in the art of anti-microbial agents, chemistry and cell biology. TNBP is the most commonly used alkyl phosphate. TNBP is further defined elsewhere in the specification.

Chemical Industries, Inc.) and TRITON® (a registered trademark of Rohm & Haas, Co). As known to those of ordinary skill in the art, TWEEN® detergents are polyoxyethylene derivatives of fatty acid partial esters of sorbital anyhydrides generally known in the chemical and biological arts as polysorbates. Non-limiting representative examples can be found beginning on page 863, column 1, at P2690 of the 1999 Sigma Biochemicals and Reagents for Life Sciences Catalogue (Sigma-Aldrich Co., St. Louis, MO.).

TRITON® detergents are based on alkylaryl polyether alcohols, sulfonates and sulfates commonly known to those skilled in the chemical and biological arts as polyoxyethylene ethers Non-limiting examples can be found beginning on page 1037, second column, of the 1999 Sigma Biochemicals and Reagents for Life Sciences Catalogue.--

Rejections under 35 USC §112

Claims 9,26-29 and 31-36 are rejected under 35 USC §112, second paragraph, as "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention."

In response, claims 9-42 have been cancelled and new claims 43-75 have been added. The Applicants assert that the Examiners rejections under 35 USC §112, second paragraph have been rendered moot by the cancellation of claims 9-42 and addition of new claims 43-75. The Applicants have carefully considered each of the Examiner's basis for his 35 USC §112, second paragraph rejections and have drafted the new claims in consideration thereof. However, the Applicants respectfully disagree with the Examiners objection the term "biological materials" and have again used the term in new claim 43. The Applicants assert that the term "biological materials" is clear and concise as defined by the specification. Moreover, the general term "biological materials" is well known in the art and each and every example provided by the Applicants in the specification clearly fall within the well established definition of "biological materials." The Applicants have enabled the inactivation of microorganisms and pyrogens potentially found in a variety of substances of biological origin and have disclosed numerous examples thereof. Therefore, the generic term "biological materials' has been enabled in the specification. The Federal Circuit, in Hybritech, Inc. v Monoclonal Antibodies, Inc. 231 USPQ 81, stated that a term or element in a claim is not indefinite under 35 USC §112, second

paragraph if "...the claims, read in light of the specification, reasonably apprise those of ordinary skill in the art and are as precise as the subject matter permits. As a matter of law, no court can demand more."[2] Therefore, when considered in light of the present specification, what constitutes a "biological material" would be well understood to persons having ordinary skill in the art. However, it should be understood, that the term "biological material" is not limited to what is disclosed by the specification and may include other biological materials. Rather the specification only serves as a guide to apprise those of ordinary skill in the art as to the general class of biological materials disclosed by the teachings of the present application. Consequently, the Applicants respectfully request that the Examiner re-considered his objection to the term "Biological materials" as used in claim 43 of the present application.

Rejections under 35 USC §102

Turning now to the Examiners rejections under 35 USC §102 (b). Claims 9-42 are rejected under 35 USC §102, as being anticipated by Isaksson et al. (U.S. Patent 5,817,765). Claims 9-42 have been canceled and new claims 43-74 have been added.

"Anticipation is established only when a single prior art reference discloses expressly or under the principles of inherency, each and every element of the claimed invention." RCA Corp. v. Applied Digital Data Systems, Inc., (1984, CAFC) 221 U.S.P.Q. 385. The standard for lack of novelty, that is, for "anticipation," is one of strict identity. To anticipate a claim, a patent or a single prior art reference must contain all of the essential elements of the particular claims. Schroeder v. Owens-Corning Fiberglass Corp., 514 F.2d 901, 185 U.S.P.Q. 723 (9th Cir. 1975); and Cool-Fin Elecs. Corp. v. International Elec. Research Corp., 491 F.2d 660, 180 U.S.P.Q. 481 (9th Cir. 1974). In the present Office Action, the Examiner's rejection is based on the Isaksson et al. reference, which fails to show all of the essential elements of the instant invention.

Thus, while the Isaksson et al. reference may teach similar data, the reference does not disclose a method for inactivating microorganisms and pyrogens present in biological materials using a detergent suspension *without* the simultaneous use of toxic organic solvents such as alkyl phosphates including tri-n-butyl phosphate (TNBP). The Examiner's attention is drawn to

[2] 321 USPQ 95

column 4, lines 4-17, specifically beginning at line 4 where Isaksson et al. state "[t]he virus inactivating step includes the addition of a detergent (e.g. a TWEEN® and/or a TRITON® X-100) *and* a virus inactivating chemical, e.g. tri-n-butyl phosphate (TNBP) to the protein in an aqueous solution." (Emphasis added.) Moreover, examples 1-4 specifically require the use of TNBP and the specification at column 3, lines 45 through 59 defines virus inactivating agents as dialkyl- or trialkylphosphates including TNBP and distinguish TNBP compounds over detergents by disclosing detergents separately at column 3 lines 60-65.

The Applicants' new claims include the added limitation of "incubating said biological material in the presence of an alkyl phosphate-free detergent solution" to more thoroughly distinguish itself from Isaksson et al. Therefore, the Applicants respectfully assert that the Examiner's rejection under 35 USC §102 (b) has been traversed and the present claims and are patently distinguish over the Isaksson et al. reference.

Rejections under 35 USC §103

Turning now to the Examiner's rejection of claims 9-40 under 35 USC § 103 as being unpatentable over Michalski et al. (US 5,304,372). To reject a claimed invention as obvious, a patent examiner must establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in prior art cited by the examiner or in knowledge generally available to one of ordinary skill in the art, to modify the reference, or combine the reference being relied on to reject the claimed invention. Secondly, there must be a reasonable expectation of success. Finally, the prior art reference or combination of references must teach or suggest all of the requirements of the claimed invention. Moreover, a determination of motivation to support an obviousness rejection requires a factual finding that a skilled artisan has knowledge of the principle of the invention. In re Werner Kotzab,(Fed. Cir. June. 20, 2000). In the present case, the Applicants respectfully assert that the Examiner's 35 USC § 103 rejection is now moot in view of new claims 43-75.

Conclusion

Therefore, all claims presently on file in the subject application are in condition for immediate allowance, and such action is respectfully requested.

If it is felt for any reason that direct communication with Applicant's attorney would serve to advance prosecution of this case to finality, the Examiner is invited to call the undersigned attorney at the below listed telephone number.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 16-2230.

Respectfully submitted,

Dated: November 21, 2000

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